

### **REMARKS**

Reconsideration of this application is respectfully requested.

The U.S. Patent and Trademark Office ("USPTO") issued a Final Office Action dated January 16, 2004 ("the Office Action"). Applicants filed a Response to Final Office Action on June 15, 2004 and a Notice of Appeal on July 16, 2004. The USPTO issued an Advisory Action dated September 3, 2004 ("the Advisory Action").

Upon entry of the foregoing amendment, claims 6-16 are pending. Claims 6, 7 and 11 are amended.

Applicants respectfully request entry of the above amendment and submit that the above amendment does not constitute new matter. Support for the amendment to claim 7 can be found, *inter alia*, in the specification on page 4, lines 4-6.

### **Rejection under 35 U.S.C. § 102**

The Office Action maintained the rejection of claims 6-16 under 35 U.S.C. § 102(b) as allegedly anticipated by Takata et al., *The Beneficial Effects of Atrial Natriuretic Peptide on Arrhythmias and Myocardial High-Energy Phosphates After Reperfusion*, 32 CARDIOVASCULAR RESEARCH, 286-293 (1996) ("Takata"). This rejection of claims 6-16 was maintained in the Advisory Action. In particular, the Advisory Action states that

Takata et al reference discloses all the elements of the claim expressly except the element "reducing an infarct region," which is inherent in the disclosure. Such a reference is still anticipatory.

Advisory Action, page 3. Applicants respectfully traverse this rejection.

Anticipation can be established only by a single reference that discloses each and every element of the claimed invention, either expressly or inherently. *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997); MPEP § 2131 at 2100-73 (8<sup>th</sup> ed., Rev. No. 2). If a single element required by the claim is missing in the reference, there can be no anticipation. *See Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 716, 223 USPQ 1264, 1271-72 (Fed. Cir. 1984).

"Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient." *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1269, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991) (citations omitted).

Applicants respectfully submit that independent claims 6 and 11, as amended, are not anticipated by Takata, either expressly or inherently.

Applicants have amended claim 6 to delete "or prophylaxis" from the phrase "[a] method of treatment ~~or prophylaxis~~ of ischemic heart disease." In addition, Applicants have amended claim 6 to delete "before the initiation of" from the phrase "which has an effect of reducing an infarct region, ~~before the initiation of~~, during and/or following ischemia reperfusion therapy."

Applicants have furthermore amended claim 11 to delete "or has a potential risk of suffering from" from the phrase "[a] method for reducing an infarct region or suppressing enlargement of an infarct region in the heart of a patient who is suffering from ~~or has a potential risk of suffering from~~ infarct resulting from ischemic necrosis." Also, Applicants have amended claim 11 to delete "before the initiation of" from the phrase "an amount effective for reducing the infarct region or suppressing enlargement of an infarct region to said patient ~~before the initiation of~~, during and/or following ischemia reperfusion."

Therefore, amended claims 6 and 11, which recite "reducing an infarct region," require the existence of an infarct region. By contrast, Takata does not disclose, either expressly or inherently, the existence of an infarct region. The existence of an actual infarct region is completely absent from Takata. Thus, Takata does not disclose, either expressly or inherently, reducing such an infarct region. Consequently, Takata does not anticipate, either expressly or inherently, the instant invention because it does not contain each and every element of the claimed invention.

However, the Advisory Action states:

In general infarction is a cause of ischemia and reperfusion injury. Takata et al.'s method protects the myocardial ischemia and reperfusion injury by administering ANP, therefore, it would also have an effect on the infarction caused by the ischemia and reperfusion injury as claimed in the current invention . . . .

Advisory Action, page 3.

As an initial matter, Applicants respectfully point out that the above-cited statement "infarction is a cause of ischemia and reperfusion injury" is incorrect. Rather, infarction is generally a result, not a cause, of ischemia and reperfusion.

Applicants respectfully disagree with the position set forth in the Advisory Action that Takata discloses that "it [ANP] would also have an effect on the infarction caused by the ischemia and reperfusion injury as claimed in the current invention." *Id.* There is no infarction region disclosed, either expressly or inherently, in Takata. Thus, there is no infarction on which the ANP could have an effect in Takata. The USPTO does not set forth any reason as to why one of ordinary skill in the art would recognize that an infarction is necessarily present in the disclosure of Takata. As stated above, in establishing inherency in anticipation, "[t]he mere fact that a certain thing *may* result from a given set of circumstances is not sufficient." *Continental Can*, 948 F.2d at 1269, 20 USPQ2d at 1749 (citations omitted).

Similarly, Applicants respectfully disagree with the position stated by the Advisory Action that Takata discloses that "[t]he practice of Takata's method will result to an effect on the size of the infarction." Advisory Action, page 3. As the existence of an infarction region is not disclosed in Takata either expressly or inherently, there is no infarction on which Takata's method has an effect, such as an effect on infarction size.

Therefore, Takata does not disclose, either expressly or inherently, each and every element of amended independent claims 6 and 11 because it does not disclose "reducing an infarct region." Accordingly, claims 6 and 11, as well as dependent claims 7-10 and 12-16, are in condition for allowance.

Applicants respectfully submit that any alleged argument of anticipation has been effectively rebutted because Takata does not disclose each and every element of the claimed invention. Thus, Applicants respectfully request that the rejection under 35 U.S.C. § 102(b) be withdrawn.

## CONCLUSION

Applicants respectfully request entry of the above claim amendments. In view of the above remarks, early notification of a favorable consideration is respectfully requested.

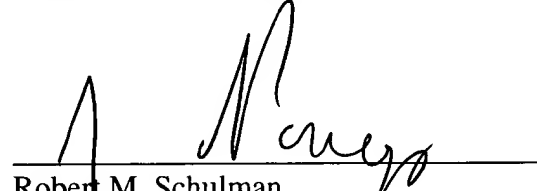
All of the stated grounds of rejection have been properly traversed, accommodated or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned, at the telephone number listed below, to conduct an interview in an effort to expedite prosecution in connection with the present application. The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 50-0206.

Respectfully submitted,

Dated: December 16, 2004

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